
EXHIBIT D

Claim 19

A drug delivery composition comprising a fiber,

IV. **WARNINGS AND PRECAUTIONS**

The warnings and precautions can be found in the SYNERGY™ Everolimus-Eluting Platinum Chromium Coronary Stent System labeling.

V. **DEVICE DESCRIPTION**

The SYNERGY™ Everolimus-Eluting Platinum Chromium Coronary Stent System (SYNERGY) is a device/drug combination product that provides a mechanical structure for vascular lumen support (primary mode of action) and a pharmacological agent (everolimus) targeted towards reducing the injury response. The System consists of a drug/polymer-coated balloon-expandable stent, pre-mounted on a Monorail™ (MR) or Over-The-Wire (OTW) delivery catheter. The stent is made from a platinum chromium alloy (PtCr). The drug/polymer coating consists of a bioabsorbable polymer, poly (D,L-lactide-co-glycolide) (PLGA), and the active pharmaceutical ingredient, everolimus. The characteristics of the SYNERGY stent system are described in Table V-T1.

Table V-T1: SYNERGY™ Everolimus-Eluting Platinum Chromium Coronary Stent System Product Description

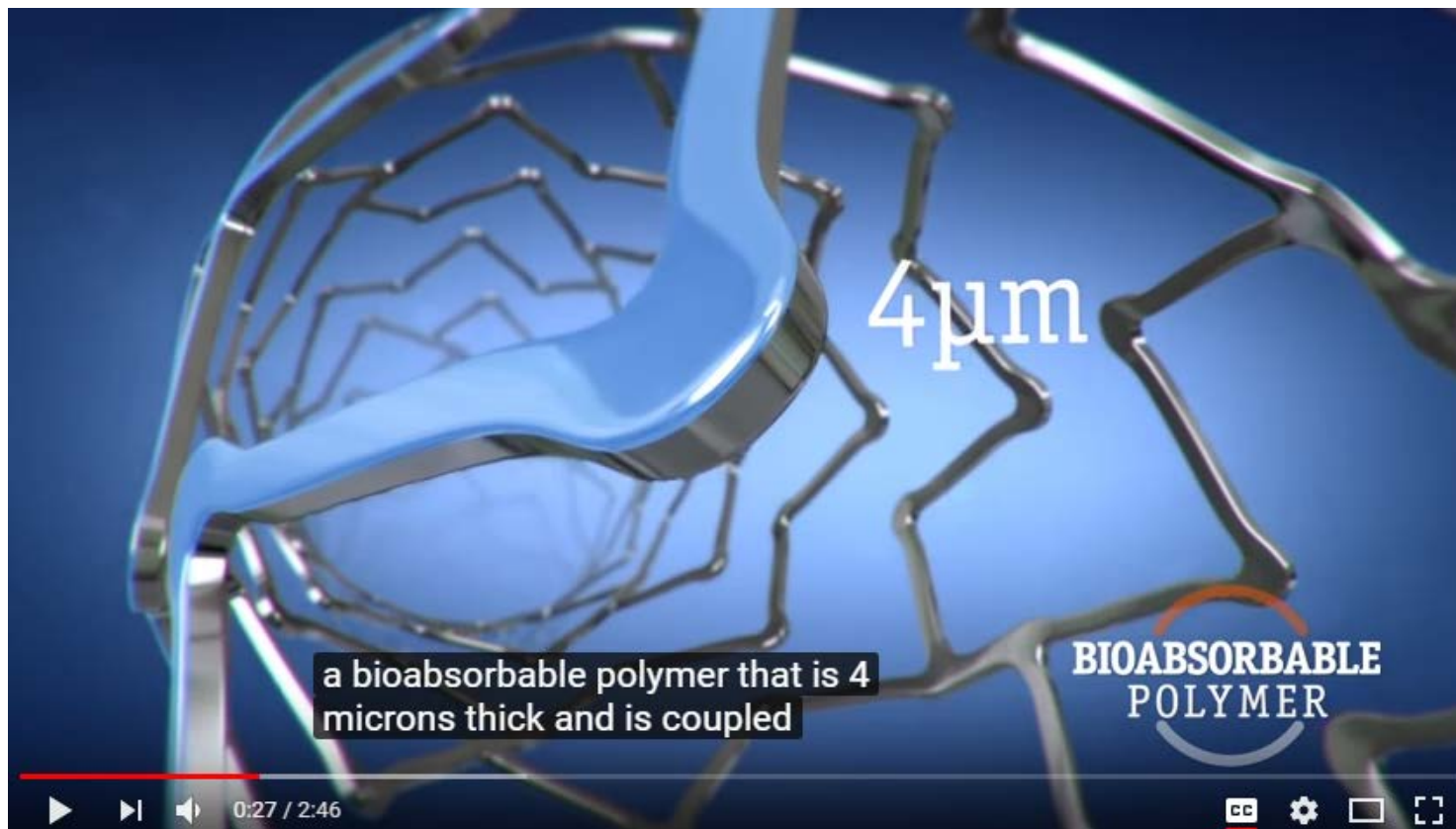
	SYNERGY Monorail Stent Delivery System	SYNERGY Over-the-Wire Stent Delivery System
Available Stent Lengths (mm)	8, 12, 16, 20, 24, 28, 32, 38	
Available Stent Diameters (mm)	2.25, 2.50, 2.75, 3.00, 3.50, 4.00	
Stent Material	Platinum Chromium Alloy (PtCr)	
Stent Strut Thickness	0.074 mm for diameters 2.25 mm to 2.75 mm 0.079 mm for diameters 3.00mm to 3.50 mm 0.081 mm for diameter of 4.00 mm	
Drug Product	An abutlunal (outer surface of the stent) coating of a polymer carrier with approximately 1 µg of everolimus per mm ² of total stent surface area with a maximum nominal drug content of 287.2 µg on the largest stent (4.00 x 38 mm).	
	Delivery System	
Effective Length	144 cm	
Delivery System Y-Adapter Ports	Single access port to inflation lumen. Guidewire exit port is located approximately 25 cm from tip. Designed for guidewire ≤0.014 inches (0.36 mm)	Y-Connector (Side arm for access to balloon inflation/deflation lumen. Straight arm is continuous with shaft inner lumen). Designed for guidewire ≤0.014 inches (0.36 mm)
Stent Delivery	A balloon, with two radiopaque balloon markers, nominally placed 0.4 mm (0.016 inches) beyond the stent at each end.	
Balloon Inflation Pressure	Nominal Inflation Pressure: • Diameters 2.25 mm, 2.50 mm, 2.75 mm, 3.00 mm, 3.50 mm, 4.00 mm: 11 atm (1117 kPa) Rated Burst Inflation Pressure: • Diameters 2.25 mm – 2.75 mm: 18 atm (1827 kPa) • Diameters 3.00 mm – 4.00 mm: 16 atm (1620 kPa)	

DEVICE DESCRIPTION

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Claim 19

A drug delivery composition comprising a fiber,



Sources: <http://www.bostonscientific.com/en-US/products/stents--coronary/bioabsorbable-polymer-stent.html>

Claim 19

wherein said fiber comprises an **emulsion consisting essentially of a gel** or hydrogel

IV. WARNINGS AND PRECAUTIONS

The warnings and precautions can be found in the SYNERGY™ Everolimus-Eluting Platinum Chromium Coronary Stent System labeling.

V. DEVICE DESCRIPTION

The SYNERGY™ Everolimus-Eluting Platinum Chromium Coronary Stent System (SYNERGY) is a device/drug combination product that provides a mechanical structure for vascular lumen support (primary mode of action) and a pharmacological agent (everolimus) targeted towards reducing the injury response. The System consists of a drug/polymer-coated balloon-expandable stent, pre-mounted on a Monorail™ (MR) or Over-The-Wire (OTW) delivery catheter. The stent is made from a platinum chromium alloy (PtCr). The drug/polymer coating consists of a bioabsorbable polymer, poly (D,L-lactide-co-glycolide) (PLGA), and the active pharmaceutical ingredient, everolimus. The characteristics of the SYNERGY stent system are described in **Table V-T1**.

DEVICE DESCRIPTION

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Table V-T1: SYNERGY™ Everolimus-Eluting Platinum Chromium Coronary Stent System Product Description

	SYNERGY Monorail Stent Delivery System	SYNERGY Over-the-Wire Stent Delivery System
Available Stent Lengths (mm)	8, 12, 16, 20, 24, 28, 32, 38	
Available Stent Diameters (mm)	2.25, 2.50, 2.75, 3.00, 3.50, 4.00	
Stent Material	Platinum Chromium Alloy (PtCr)	
Stent Strut Thickness	0.074 mm for diameters 2.25 mm to 2.75 mm 0.079 mm for diameters 3.00mm to 3.50 mm 0.081 mm for diameter of 4.00 mm	
Drug Product	An abluminal (outer surface of the stent) coating of a polymer carrier with approximately 1 µg of everolimus per mm ² of total stent surface area with a maximum nominal drug content of 287.2 µg on the largest stent (4.00 x 38 mm).	
Effective Length	Delivery System 144 cm	
Delivery System Y-Adapter Ports	Single access port to inflation lumen. Guidewire exit port is located approximately 25 cm from tip. Designed for guidewire ≤0.014 inches (0.36 mm)	Y-Connector (Side arm for access to balloon inflation/deflation lumen. Straight arm is continuous with shaft inner lumen). Designed for guidewire ≤0.014 inches (0.36 mm)
Stent Delivery	A balloon, with two radiopaque balloon markers, nominally placed 0.4 mm (0.016 inches) beyond the stent at each end.	
Balloon Inflation Pressure	Nominal Inflation Pressure: • Diameters 2.25 mm, 2.50 mm, 2.75 mm, 3.00 mm, 3.50 mm: 11 atm (1117 kPa) Rated Burst Inflation Pressure: • Diameters 2.25 mm – 2.75 mm: 18 atm (1827 kPa) • Diameters 3.00 mm – 4.00 mm: 16 atm (1620 kPa)	

An embodiment of the invention provides a bi-component fiber where the inner bore of the fiber, i.e., inside diameter of the fiber, comprises a gel or hydrogel and the outer wall of the fiber comprises a biodegradable polymer. As used herein, the term “gel” refers to a colloidal system with at least two phases, one of which forms a continuous three-dimensional network that acts as an elastic solid. As used herein, the term “hydrogel” refers to a colloid in which a dispersed phase (colloid) is combined with a continuous phase (water) to produce a viscous jellylike product.

Claim 19

wherein said fiber comprises an **emulsion consisting essentially of a gel** or hydrogel

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V. **DEVICE DESCRIPTION**

The SYNERGY™ Everolimus-Eluting (SYNERGY) is a device/drug combination for vascular lumen support (primary use) (everolimus) targeted towards reducing drug/polymer-coated balloon-expandable stent, pre-mounted on a Monorail™ (MR) or Over-The-Wire (OTW) delivery catheter. The stent is made from a platinum chromium alloy (PtCr). The drug/polymer coating consists of a bioabsorbable polymer, poly (D,L-lactide-co-glycolide) (PLGA), and the active pharmaceutical ingredient, everolimus. The characteristics of the SYNERGY stent system are described in Table V-T1.

Drug Product

An abluminal (outer surface of the stent) coating of a polymer carrier with approximately 1 µg of everolimus per mm² of total stent surface area with a maximum nominal drug content of 287.2 µg on the largest stent (4.00 x 38 mm).

Table V-T1: SYNERGY™ Everolimus-Eluting Platinum Chromium Coronary Stent System
Product Description

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Effective Length	144 cm	
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